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| EXAMINER | |
|---|---|
| EREZO, DARWIN P | |

| ART UNIT | PAPER NUMBER |
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| 3773 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/077,618 | FEIGL, ALEXANDER J. | |
| | Examiner | Art Unit | |
| | Darwin P. Erezo | 3773 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *07 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-11,31-41 and 64-91* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,31-41 and 64-89* is/are rejected.

7)☒ Claim(s) *90 and 91* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. The restriction requirement provided in the Office action mailed on 7/11/07 is withdrawn. See the Examiner Interview Summary Record mailed on 8/6/07 for details.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

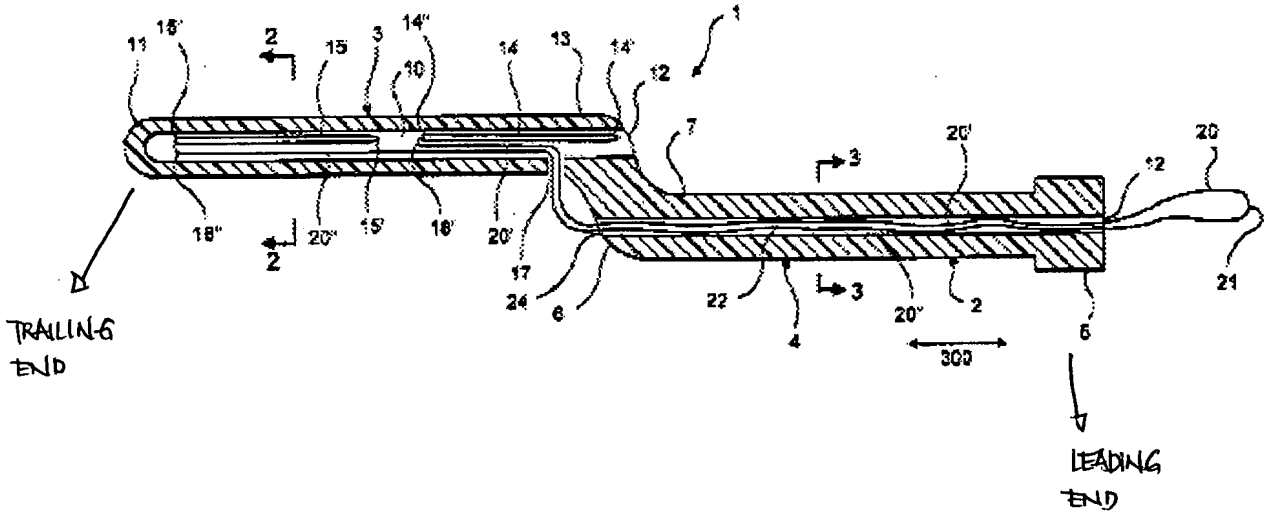
> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3-6, 64, 66-69, 70 and 72-75 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,980,539 to Kontos.

(claims 1, 64 and 70) Kontos discloses a medical device comprising a body **1** having a leading end **2** and a trailing end **11** (as shown in the attached figure below); a lumen **22** extending from a first lumen opening **24** formed in the body to a second lumen opening **12** formed in the body (Fig. 1); a first needle guide channel **10** extending from a first needle guide channel opening **12** formed in the body to a second needle guide channel formed in the body **17**; and a needle **14** having a leading end a trailing end (see attached figure below), the trailing end of the needle being connected to a length of suture **20**, the leading end being the first end of the needle to penetrate tissue, the needle being backloaded into the first needle guide channel such that the trailing end of the body is closer to the trailing end of the needle than to the leading end of the needle (see attached figure below), the suture being threaded through the lumen such that

when a portion of the length of suture that is unsurrounded and positioned outside of the body is pulled, the needle will be advanced out of the first needle guide channel; the medical device being configured such that the first needle guide channel opening and the second needle guide channel opening are capable of being directly exposed to a patient's tissue. It is also noted that the suture **20** can be rotated and pulled to the right of the device shown in Fig. 1, which would in turn force the needle out of the channel in a leftward direction.

With regards to the limitation that the leading end of the body is the first end that will be inserted into a patient during a procedure, it is noted that the "interpreted" leading end, as shown in the figure below, is fully capable of being the first end inserted into a patient when the device is used to suture internal tissues or organs. That is, the "leading end" can be inserted into the patient first, then followed by the rest of the device. Afterwards, the device can be manipulated into position from within the body cavity of the patient.



(claims 3, 4, 66, 67 and 72) The proximal portion **5** having flange, as shown in Fig. 1, acts as a handle; wherein said flange is viewed as a connecting piece to said body.

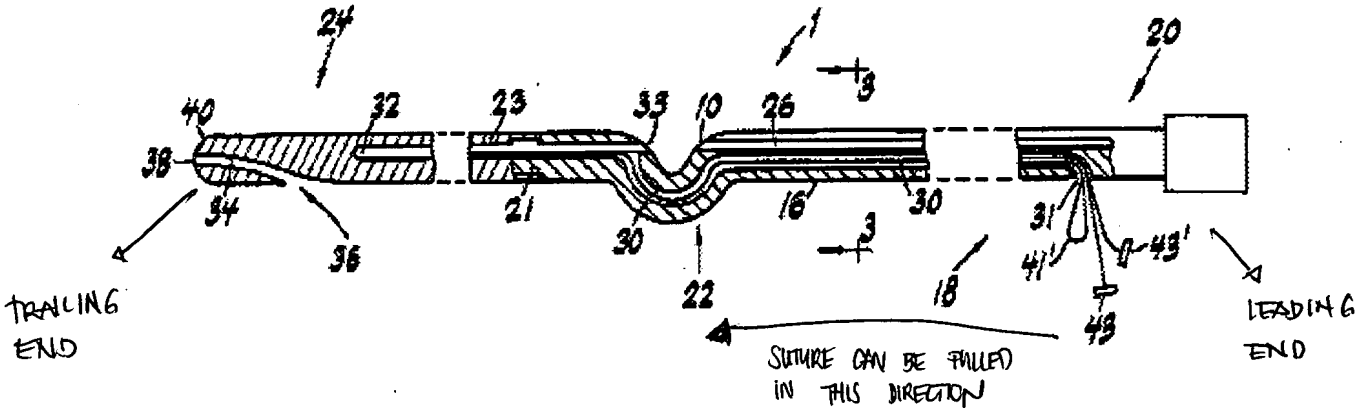
(claims 5, 68, 73 and 74) Kontos discloses that the tube portion **4** that comprises said flange **5** is flexible (col. 4, line 3), which makes the handle portion bendable.

(claims 6, 69 and 75) The distal end of the body is tapered.

4. Claims 31-41 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,997,555 to Kontos.

(claim 31) Kontos discloses a medical device comprising a body **1** having a leading end **18** and a trailing end **24** (as shown in the attached figure below); a lumen **30** extending from a first lumen opening **31** formed in the body to a second lumen opening formed in the body (shown in Fig. 1); a first needle guide channel **32** extending from a first needle guide channel opening **33** formed in the body; and a needle **37** having a leading end a trailing end (see attached figure below), the trailing end being connected to a length of suture **41**, the leading end being the first end of the needle to penetrate tissue, the needle being backloaded into the first needle guide channel such that the trailing end of the body is closer to the trailing end of the needle than to the leading end of the needle (see attached figure below), the suture being threaded through the lumen such that when a portion of the length of suture that is unsurrounded and positioned outside of the body is pulled in a first direction (Fig. 1, the suture can be pulled to the left), the needle will be advanced out of the first needle guide channel in a

second direction (Fig. 1, to the right); wherein the first direction would be positive longitudinal component and the second direction is a negative longitudinal component.




(claim 32) Fig. 7 shows a needle guide channel that is arcuate shape in use.

(claims 33 and 34) The proximal portion **20** includes a flange, as shown in Fig. 1, which acts as a handle; wherein said flange is viewed as a connecting piece to said body.

(claim 35) Kontos discloses that the tube portion **16** that comprises said flange **5** is flexible (col. 4, line 61), which makes the handle portion bendable.

(claim 36) The distal end of the body is tapered.

(claims 37-41) Fig. 25 of Kontos discloses an embodiment having a first and second guide channel, wherein the channels are arcuate, circumferentially spaced and equidistant from each other. It should also be noted that the pull cord **142** can be turned around and pulled downward, which would still be in an opposite direction to that of the needles.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 2, 65 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Kontos ('539) reference, as applied to the rejection to claim 1 above, and in view of the other Kontos ('555) reference.

The '539 reference discloses all the limitations of the claim except for the needle guide channel having an arcuate shape. However, the '555 reference shows an embodiment where the distal portion of the device is bent in use, and wherein a needle guide channel within the distal portion is arcuate (see Fig. 7). The distal portion is bent in order for the device to fit within the blood vessel. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of the '539 reference to include a distal portion having said needle guide channel in a bent/arcuate configuration because it would allow the device to better fit

within the blood vessel. Furthermore, changing a known needle guide channel configuration for another known needle guide channel configuration will provide predictable results.

8. Claims 7, 10, 11, 76, 79, 80, 81 and 83-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kontos ('539).

(claims 7 and 76) Fig. 1 of Kontos discloses a single needle guide channel having a first needle guide channel opening and a second needle guide channel opening. This embodiment is silent with regards to the device having an additional needle guide channel. However, Fig. 17 of Kontos discloses an embodiment that does include a first and second needle guide channels. The difference between the embodiments shown Fig. 1 and Fig. 17 lies in the fact that the embodiment shown in Fig. 17 fails to teach the first or the second needle guide channels having a second needle guide channel opening. A second needle guide channel opening is only shown in Fig. 1. However, Fig. 17 is merely a modification of another embodiment shown in Fig. 6, which like Fig. 1, only contains one needle guide channel. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the embodiment of Fig. 1 to include a second needle guide channel, since Kontos already discloses the usefulness of having a second needle guide channel in a modification to embodiment shown in Fig. 6 to form the embodiment shown in Fig. 17. One of ordinary skill in the art would be able to replicate this same modification to the embodiment shown in Fig. 1 and yield predictable results.

(claims 10, 11, 79, 80) The modification to include a second needle guide channel would have the channels arranged side by side, with the second needle guide channel openings for both channels facing the lumen opening **24**. This is viewed as being having "two" circumferentially positioned channels that are equidistant from each other (there is only one distance between two channels).

(claim 81) See the rejection to claims 1 and 7 above.

(claims 83 and 84) See the rejection to claims 3 and 4 above.

(claim 85) See the rejection to claim 5 above.

(claim 86) See the rejection to claim 6 above.

(claim 87) The modification above teaches two needle guide channels but is silent with regards to addition of a third needle channel. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add an additional third needle guide channel, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *In re Harza*, 274 F.2d, 669, 124 USPQ 378 (CCPA 1960). Moreover, this is the same type of modification to include a second needle guide channel to the an embodiment having only one needle guide channel.

9. Claims 8, 9, 77, 78, 82, 88 and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kontos ('539), as applied to the rejection to claims 7, 76 and 87 above, and in view of Kontos ('555).

The '539 reference discloses all the limitations of the claims except for the needle guide channel having an arcuate shape. However, the '555 reference shows an

embodiment where the distal portion of the device is bent in use, and wherein a needle guide channel within the distal portion is arcuate (see Fig. 7). The distal portion is bent in order for the device to fit within the blood vessel. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of the '539 reference to include a distal portion having said needle guide channel in a bent/arcuate configuration because it would allow the device to better fit within the blood vessel. Furthermore, changing a known needle guide channel configuration for another known needle guide channel configuration will provide predictable results.

***Allowable Subject Matter***

10. Claims 90 and 91 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

11. Applicant's arguments filed 4/25/07 have been fully considered but they are not persuasive.

Independent claims 1, 31, 64 and 70 were amended to recite "the body of the medical device having a leading end and a trailing end, the leading end of the body being the first end of the body that will be inserted into a patient during a procedure; the needle also including a trailing end and a leading end; and wherein the trailing end of the needle is closer to the trailing end of the body".

The applicant argued that neither of the Kontos references ('539 & '585) fail to disclose the recited limitation. However, this is not persuasive. As shown in Fig. 1 of the '539 reference, the proximal end **2** and the distal end **11** can be interpreted as "the leading end" and "the trailing end", respectively. That is, distal end **11** is fully capable of being the called the "leading end" because it is *fully capable* of being the first end inserted into the patient when the tissue to be sutured is located within the body cavity. When suturing within the body cavity, either end of the device can be inserted initially since the entire device will end up being inside the body cavity and that the device can still manipulated into position once inside the body cavity. The same argument applies for Fig. 1 of the '585 device.

With regards to the rejections for claims 7, 10, 11, 76, 70, 80, 81 and 83-87, the applicant argue that Kontos '539 fails to teach the first needle in a first needle guide channel being connected to a first length of suture, and a second needle in a second needle guide channel, the second needle being connected to a second length of suture that is separate from the first length of suture. This is not persuasive because Kontos '539 does disclose a first needle **81** that is connected to suture **87**, while the second needle **82** in a separate guide channel is connected to suture **20**, which is separate from suture **87**.

***Conclusion***

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezo whose telephone number is (571) 272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezo/
Examiner
Art Unit 3773

de